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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/733,869	12/08/2000	Georgia L. Helmer	5051-473	3142

20792 7590 12/23/2004

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EXAMINER
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MARVICH, MARIA

ART UNIT	PAPER NUMBER
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1636

DATE MAILED: 12/23/2004

Please find below and/or attached an Office communication concerning this application or proceeding.

## Office Action Summary

Application No.

09/733,869

Applicant(s)

HELMER ET AL.

Examiner

Maria B Marvich, PhD

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

### Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

### Status

- 1) ☐ Responsive to communication(s) filed on \_\_\_\_.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

### Disposition of Claims

- 4) ☒ Claim(s) 1-18 is/are pending in the application.
- 4a) Of the above claim(s) \_\_\_\_ is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_ is/are allowed.
- 6) ☒ Claim(s) 1-18 is/are rejected.
- 7) ☐ Claim(s) \_\_\_\_ is/are objected to.
- 8) ☐ Claim(s) \_\_\_\_ are subject to restriction and/or election requirement.

### Application Papers

- 9) ☒ The specification is objected to by the Examiner.
- 10) ☒ The drawing(s) filed on 20 August 2002 is/are: a) ☐ accepted or b) ☒ objected to by the Examiner.  
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).  
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

### Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some \* c) ☐ None of:
- ☐ Certified copies of the priority documents have been received.
  - ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_.
  - ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

\* See the attached detailed Office action for a list of the certified copies not received.

### Attachment(s)

- ☒ Notice of References Cited (PTO-892)
- ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- ☒ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)  
Paper No(s)/Mail Date 8/20/02.
- ☐ Interview Summary (PTO-413)  
Paper No(s)/Mail Date. \_\_\_\_.
- ☐ Notice of Informal Patent Application (PTO-152)
- ☐ Other: \_\_\_\_.

### **DETAILED ACTION**

Claims 1-18 are pending in the application.

#### ***Information Disclosure Statement***

An IDS filed 8/20/02 has been identified and the documents considered. The signed and initialed PTO Form 1449 has been mailed with this action.

#### ***Drawings***

Figure 8 is objected to under 37 CFR 1.83(a) because it fails to show any details as described in the specification. Any structural detail that is essential for a proper understanding of the disclosed invention should be shown in the drawing. MPEP § 608.02(d). The image is a photograph of a Southern blot and arrows indicate bands. However, no bands are visible. A proposed drawing correction or corrected drawings are required in reply to the Office action to avoid abandonment of the application. The objection to the drawings will not be held in abeyance.

#### ***Specification***

The disclosure is objected to because of the following informalities: there is a large blank space following the heading for Example 23 on page 38 and similarly smaller blank spaces have been identified on pages 10, 11 40, 41 and 48. It is not clear if there were text or tables on these pages that have been omitted or if these are intentional blanks. Appropriate correction is required.

***Claim Rejections - 35 USC § 112, second paragraph***

The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

Claims 1-18 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

Claim 1 is vague and indefinite in that the metes and bounds of "recombination site" are unclear. It is unclear whether it is required that the sites are involved in site-specific recombination or can sites for random integration or homologous recombination be used as "recombination sites" in the instant invention? Upon reading the specification, it appears the invention is directed to methods featuring recombination sites recognized by site-specific recombinase enzymes.

Claims 1 and 3 are vague and indefinite in that the metes and bounds of "a target site flanked by a single recombination site" are unclear. It is unclear how a target site can be "flanked" on one side by a "single" recombination site. Taken literally, the site should have recombination sites on its sides.

Claims 8-10 recite the limitation "said recombinase" in claim 1. There is insufficient antecedent basis for this limitation in the claim.

Claim 13 is vague and indefinite in that the metes and bounds of "cells, some of which are transformed" as well as "at least one transformed cell" are unclear. It is unclear if these

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recited transformed cells have been previously transformed or this refers to the cells following transformation recited in claim 1, step (b).

***Claim Rejections - 35 USC § 102***

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(e) the invention was described in (1) an application for patent, published under section 122(b), by another filed in the United States before the invention by the applicant for patent or (2) a patent granted on an application for patent by another filed in the United States before the invention by the applicant for patent, except that an international application filed under the treaty defined in section 351(a) shall have the effects for purposes of this subsection of an application filed in the United States only if the international application designated the United States and was published under Article 21(2) of such treaty in the English language.

Claims 1, 2, 4, 6, 7 and 9-18 are rejected under 35 U.S.C. 102(e) as being anticipated by Baszczyński et al (6,187,994; see entire document).

Baszczyński et al teach compositions and methods for genetic modification of plants for targeted integration of nucleotide sequences into a plant. Transfer cassettes comprising a nucleotide of interest flanked by recombination sites such as FRT are used to transfer the plant at a target site (see e.g. col line 52-60). The target site contains at least a set of non-identical recombination sites corresponding to those on the transfer cassette. Recombination occurs in the presence of recombinase such as FLP (see e.g. col 3, line 27-32). The target site and targeting cassette are characterized by being flanked by recombination sites (see e.g. col 3, line 40-50). The stable plant cells are produced by Agrobacterium transformation (see e.g. col 10, line 64 through col 11, line 3). Targeting cassettes are also introduced into the cells by Agrobacterium mediated transformation and comprise selectable markers for selection by antibiotic resistance (see e.g. col 8, line 41-44 and figure 2). Plants include dicot plants with a genome size of greater

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than 500-mega base s (see e.g. col 9, line 35 through col 10, line 52). Target cell lines *in vitro* were bombarded with a reporter gene flanked by corresponding FRT sites (see e.g. example ). Cells transformed are selected and grown into plants and seeds harvested and includes pollen (see e.g. col 10, line 11-63).

Claims 1-3, 5, 8 and 11-17 are rejected under 35 U.S.C. 102(e) as being anticipated by Ow et al (US 6,746,870; see entire document).

Ow et al teach methods for containing specific and stable integration of nucleic acids into eukaryotic cells such as plant cells using integrase (see e.g. abstract). A single *att* recombination site flanking a heterologous target site and a single *att* recombination site flanking a nucleotide of interest are presented in the presence of integrase in dicot tobacco plants (see e.g. figure 5). However, multiple other plant target cells are contemplated (see e.g. col 9, line 63-col 10, line 3). Selectable markers are included in targeting cassettes for selection of resistance (see e.g. col 13, line 3- 16). Constructs are introduced into the cells by Agrobacterium mediated transformation (see e.g. col 14, line 7-23). Plant cells are transformed *in vitro* and then are regenerated to whole plants and seeds (see e.g. col 5, line 56-61 and col 15, line 5-23).

### ***Conclusion***

No claims allowed.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Maria B Marvich, PhD whose telephone number is (571)-272-0774. The examiner can normally be reached on M-F (6:30-3:00).


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If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Remy Yucel, PhD can be reached on (571)-272-0781. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

Maria B Marvich, PhD  
Examiner  
Art Unit 1636

December 18, 2004

  
GERRY LEFFERS  
PRIMARY EXAMINER